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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KATHRYN F. SYKES,
KATHERINE S. HALE, and STEPHEN A. JOHNSTON

Appeal 2008-2539
Application 10/688,058
Technology Center 3600

Decided: June 9, 2008

Before DEMETRA J. MILLS, LORA M. GREEN, and
RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 48 and 88-91. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The claims are directed to vaccines comprising one or more *Borrelia* antigenic polypeptides (“antigen”) identified by their corresponding sequence identifier (“SEQ ID NO”).

Claims 48 and 88-91 are pending and stand rejected under 35 U.S.C. § 102(b) as anticipated by Choi (WO98/59071, Dec. 30, 1998). Claim 48, which reads as follows, is representative of the appealed claims:

48. A vaccine composition comprising a pharmaceutically acceptable carrier and at least a first *Borrelia* antigen or a first polynucleotide encoding the first *Borrelia* antigen, wherein the first *Borrelia* antigen comprises an amino acid sequence of SEQ ID NO:2, SEQ ID NO:4, SEQ ID NO:6, SEQ ID NO:8, SEQ ID NO:10, SEQ ID NO:12, SEQ ID NO:14, SEQ ID NO:16, SEQ ID NO:18, SEQ ID NO:20, SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26, SEQ ID NO:28, SEQ ID NO:30, SEQ ID NO:32, SEQ ID NO:34, SEQ ID NO:36, SEQ ID NO:38, SEQ ID NO:40, SEQ ID NO:42, SEQ ID NO:44, SEQ ID NO:46, SEQ ID NO:48, SEQ ID NO:50, SEQ ID NO:52, SEQ ID NO:54, SEQ ID NO:56, SEQ ID NO:58, SEQ ID NO:60, SEQ ID NO:62, SEQ ID NO:64, SEQ ID NO:66, SEQ ID NO:68, SEQ ID NO:70, SEQ ID NO:72, SEQ ID NO:74, SEQ ID NO:76, SEQ ID NO:78, SEQ ID NO:80, SEQ ID NO:82, SEQ ID NO:84, SEQ ID NO:86, SEQ ID NO:88, SEQ ID NO:90, SEQ ID NO:92, SEQ ID NO:94, SEQ ID NO:96, SEQ ID NO:98, SEQ ID NO:100, SEQ ID NO:102, SEQ ID NO:104, SEQ ID NO:106, SEQ ID NO:108, SEQ ID NO:110, SEQ ID NO:112, SEQ ID NO:114, SEQ ID NO:117, SEQ ID NO:119, SEQ ID NO:121, SEQ ID NO:123, SEQ ID NO:125, SEQ ID NO:127, SEQ ID NO:129, SEQ ID NO:131, SEQ ID NO:133, SEQ ID NO:135, SEQ ID NO:137, or SEQ ID NO:139 or fragments thereof; and wherein the vaccine composition does not contain a whole cell lysate of a *Borrelia* pathogen.

ISSUE ON APPEAL

The Examiner contends that Choi describes a vaccine composition comprising a polypeptide which is identical to one of the polypeptide sequences recited in claim 48, anticipating the claimed subject matter. Appellants contend that Choi is not enabling for a vaccine composition

ANTICIPATION

Claims 48 and 88-91 stand rejected under 35 U.S.C. § 102(b) as anticipated by Choi (Ans. 3).

Findings of Fact (“FF”)

1. Choi teaches vaccines for the prevention or attenuation of Lyme disease, a disease caused by the spirochete *Borrelia burgdorferi* (Choi, at 1).
2. The vaccine can comprise “one or more *B. burgdorferi* polypeptides shown in Table 1, or fragments thereof” which are “present in an amount effective to elicit an immune response to members of the *Borrelia* genus in an animal” (Choi, at 4, ll. 13-16; *see* Ans. 3).
3. There are no working examples in Choi where a polypeptide was utilized to induce an immune response, but Choi explains how it would be done (Choi, at 4, l. 12 to 5, l. 1; at 53-54).
4. The 810 amino acid polypeptide listed in Table 1 on page 134 of Choi “is identical to the instantly claimed SEQ ID NO:8, and comprises a fragment of instantly claimed SEQ ID NO:6” (Ans. 3).
5. Choi states that any one of the polypeptides in Table 1 can be present in a vaccine (FF 1, 2), which includes the 810 amino acid polypeptide which is identical to SEQ ID NO:8 of claim 48 (FF 4).
6. Choi therefore describes a vaccine which comprises a polypeptide of SEQ ID NO: 8, meeting all the limitations of the claimed invention.

Analysis

To anticipate, every element and limitation of the claimed invention must be found in a single prior art reference, arranged as in the claim.

Karsten Mfg. Corp. v. Cleveland Golf Co., 242 F.3d 1376, 1383 (Fed. Cir. 2001). In this case, we agree with the Examiner's findings that Choi describes a vaccine and a polypeptide in it that satisfies all the limitations of claim 48 (*see* FF 1-6). Thus, we turn to Appellants' rebuttal arguments and evidence.

Appellants argue that Choi is not enabling (App. Br. 3). They state that Choi "discloses hundreds of sequences . . . [but] fails to disclose a single example where even one of these sequences was used to elicit an immune response in an animal" (*id.*). They assert that "Choi has done nothing more than venture a guess that one or more of the hundreds" of polypeptides listed in its "specification would be useful antigens in a vaccine" (*id.*).

This argument is not persuasive. A species which is specifically disclosed in a prior art reference is anticipatory even though it appears "without special emphasis in a longer list." *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1376 (Fed. Cir. 2005). As Choi states that any polypeptide shown in Table 1 can be utilized as a vaccine, it is anticipatory to the subject matter of claim 48, despite being a member of a list of other polypeptides.

Appellants state that "to obtain Appellant's claimed vaccine from Choi, a person of ordinary skill in the art would have to analyze an enormous number of *Borrellia* sequences. This is analogous to a 'needle-in-the-haystack' approach" (App. Br. 3). Appellants cite *Ex parte Garvey*,

41 USPQ 583 (Pat. & Trademark Office Bd. App. 1939) as having “found no anticipation from these types of disclosures” (App. Br. 3-4).

In *Garvey*, the Board found that the cited prior art did not anticipate the claimed invention because the claimed subject matter could “be found only by making one of a very great number of possible permutations which are covered by the reference disclosures. The likelihood of producing a composition such as here claimed from a disclosure such as shown by the Dykstra patent would be about the same as the likelihood of discovering the combination of a safe from a mere inspection of the dials thereof.” *Garvey*, 41 USPQ at 584.

The facts of this case are unlike those of *Garvey*. The disclosed 810 amino acid polypeptide is specifically listed in a table (FF 5); a vaccine composition comprising it is produced by the simple act of selecting it from a list of other polypeptides, each which has been explicitly taught as useful in a vaccine (*see* FF 2). There are no permutations necessary to discover it as there were apparently in *Garvey*.

We are also not convinced that Choi is defective because there is no working example in which a polypeptide of Table 1 was utilized to elicit an immune response (App. Br. 3, 4-5; *see* FF 3)). “[P]roof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation.” *Impax Laboratories Inc. v. Aventis Pharmaceuticals Inc.*, 468 F.3d 1366, 1382 (Fed. Cir. 2006). Thus, in this case, there is no legal requirement that Choi actually elicit an immune response; it is sufficient that Choi states that it can be done. The proper issue is whether Choi “is enabling in the sense that it describes the claimed invention sufficiently to enable a person of

ordinary skill in the art to carry out the invention.” *Impax Laboratories*, 468 F.3d at 1383.

In support of their position that the Choi is not enabling, Appellants describe various difficulties associated with immunization against *Borrelia*, including cross-reactivity and the development of autoimmunity (App. Br. 4-5). These arguments are not convincing. Claim 48 is a composition claim; there is no requirement in the claim that an immune response elicited from it be free of cross-reactivity or autoimmunity. Appellants do not otherwise identify a defect in Choi’s disclosure that would prevent any polypeptide disclosed in it as being used as a vaccine in the manner described by Choi.

We affirm the rejection of claim 48. Claims 88-91 fall with claim 48 because separate arguments were not provided for their patentability. 37 C.F.R. § 41.37(c)(vii)(1).

INDEFINITENESS

Claims 48 and 88-91 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite (Ans. 3). The Examiner contends that “claim 48 is drawn to a nonelected invention, i.e., ‘a vaccine composition comprising a first polynucleotide’” (Ans. 3).

In the Restriction dated June 24, 2005 (“Restriction”), the Examiner required Appellants to elect either “DNA compositions” or “polypeptide compositions” (Restriction 2). Appellants elected the polypeptide compositions without traverse (Response dated Nov. 23, 2005, at p. 2). Claim 48, in addition to being directed to polypeptides, also includes DNA (“polynucleotide”) which is nonelected subject matter. We do not find a

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claim with unelected subject matter to be indefinite; rather the subject matter is withdrawn from consideration (*see* 37 C.F.R. § 1.142(b)).

We reverse the rejection of claims 48 and 88-91 under 35 U.S.C. § 112, second paragraph.

CONCLUSION

We affirm the prior art rejection of claims 48 and 88-91, but reverse the rejection of these claims under § 112, second paragraph.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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